Suggestions for Organizing Information for a CCOP Application

In preparing a CCOP application, you must follow the instructions provided in the **RFA CA-07-025** (*Community Clinical Oncology Program*) and the *Application for a Public Health Service Grant* (PHS-398) (Rev. 09/2004, Interim Revision 04/2006) available at: http://grants.nih.gov/grants/forms.htm and its accompanying packet of forms.

NOTE: This edition of the PHS 398 is organized into three distinct parts, each of which is available as a separate file in MS Word and PDF versions. Applicants will need to use all three parts of the instructions to prepare a complete and acceptable application.

The PHS 398 instructions include:

Part I: *Instructions for Preparing the Application*
Part II: *Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan*
Part III: *Policies, Assurances, Definitions and Other Information*.

The suggestions and sample tables provided in this Suggestions for Organizing Information for a CCOP Application are provided as a supplement to the PHS-398 (Rev. 09/2004, Interim Revision 04/2006), NOT A REPLACEMENT. While, these suggestions and tables are not mandatory, they may help the applicant supply all the information required by the RFA while remaining within the page limitations (**see RFA-CA-07-025, Part II**, Section IV.2., Content and Form of Application Submission). Following this suggested format may assist reviewers in their evaluation of the applicant=s resources and capabilities. The tables provided in this format may be included in the application as part of the Resources, Progress Report and Human Subject Research sections, as appropriate.

NOTE**: Requirement of DUNS Numbers on NIH Applications** - Use of the Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is required when applying for Federal grants or cooperative agreements. See NIH Guide Notice dated August 14, 2003 and the DUNS Q&A (MS Word) document for more information.

NOTE: **Other Support** should NOT be submitted with the application. If this information is included in the application, the application may be returned to the applicant organization WITHOUT peer review. See PHS 398 (Rev.09/2004 Interim Revision 04/2006) **Part III** (*Policies, Assurances, Definitions, and Other Information*), G. **Just-in-Time Policy**, pages 8-9. Do NOT confuse "**Research Support**" with "**Other Support**." Although they sound similar, these parts of the application are very different. See **Part III (***Policies, Assurances, Definitions, and Other Information)* page 9.

GENERAL INSTRUCTIONS

Although formatting and submission information is provided in the PHS-398 (Rev.09/2004 Interim Revision 04/2006), some of the requirements are repeated in these instructions to emphasize the importance of some sections of the application**.** Please refer to the **RFA CA-07-025** and the PHS-398 (Rev.09/2004 Interim Revision 04/2006) **Part I, II and III** for complete instructions.

X Prepare the application using the PHS 398 MS WORD or PDF *form* pages and *format* pages as provided. *Form* pages must be identical to those provided in the PHS 398. You may substitute computer generated facsimiles for government-provided forms; however they must maintain the exact wording and format of government forms, including all captions and spacing. *Format* pages are intended to assist you in the development of specific sections of the application. Alternatively, you may create a page similar to any format provided as long as all the requisite information is included.

Font sizes on some PHS 398 form pages vary due to field or space limitations. The PHS 398 MS WORD and PDF *Form* Pages as provided are acceptable to NIH. All other sections of the application (e.g., Biographical Sketch; Literature Citations; and the Research Plan) must conform to the font and format requirements as stated in the PHS 398 (Rev.09/2004 Interim Revision 04/2006) **Part I** (*Instructions*), **Format Specifications**, on pages 17-18.

- Include all pertinent information in the text and tables. **DO NOT** use the Appendix for any material that all reviewers need to see because, this information will not be reproduced for all the reviewers. See PHS 398 (Rev. 09/2004, Interim Revision 04/2006) **Part I** (*Instructions*), **Appendix**, page 41 for more details.

- **Do not** include photographs or other materials that are not printed directly on the application page in the body of the application. Pictures or materials that are glued or taped onto the application pages are incompatible with the current duplication/scanning process. You may include black-and-white or color images in the six (6) submitted copies provided such images are printed directly on the application page and are critical to the content of the application.

  Do not submit oversized documents, materials that do not reproduce well or institutional public relations-type documents.

- Include a table of contents (see Form Page 3), so that reviewers can identify each part of the application by page number. See PHS 398 (Rev. 09/2004, Interim Revision 04/2006) **Part I** *(Instructions*), 3. **Research Grant Table of Contents**, page 28. NOTE: Do not include unnumbered pages and do not use suffixes, such as 5a, 5b.

CCOP APPLICATION DUE DATE

- Submit the applications **by August 28, 2006**.

- Affix RFA label to bottom of face page. See the Mailing Address and RFA Label Form.

- Late applications will not be accepted. Receipt dates listed in PHS 398 (Rev. 09/2004, Interim Revision 04/2006) **Part I** (*Instructions*) **Application Submission Dates**, Table 2 on pages 46-47 **DO NOT apply** to applications responding to **RFA-CA-07-025**. The application deadline is referenced in the RFA.

REVISED/RESUBMISSION (AMENDED) APPLICATIONS

An unsuccessful applicant from the previous year=s competition is a *revised/resubmission (amended)* application that **MUST** include an Introduction of **not more than three pages** that summarize the substantial additions, deletions and changes to the application. The Introduction must also include responses to the criticisms and issues raised in the summary statement. NIH allows the submission of up to two revised applications but no longer restricts those submissions to a two-year timeframe. See PHS-398 (Rev.09/2004 Interim Revision 04/2006) **Part I** (*Instructions*), **Revised/Resubmission Applications**, page 19, (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-041.html).

RENEWAL APPLICATION

An application from a currently funded CCOP is a ***renewal*** (*competing continuation*) and must include a

progress report. See PHS-398 (Rev.09/2004 Interim Revision 04/2006) **Part I** (*Instructions*), C. **Preliminary Studies/Progress Report**, page 35.

The progress report, at a minimum, should include:

X Summary of the CCOP activities and accomplishments over the previous funding period, with a clear presentation of accrual (treatment and cancer control) for each year of the previous funding period (see **Sample Tables 7A and 7B**) of the suggested format;

X An evaluation of the CCOP performance by each of its affiliated Research Bases;

X Complete description of how the applicant has met the special cooperative agreement terms and conditions of the award; and

X Report and table on the enrollment of women/men and on ethnicity/race of research participants during the previous funding period (see PHS 398 (Rev.09/2004 Interim Revision 04/2006) **Part II** (*Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan*), page 19, C. **What Inclusion/Enrollment Table Should Principal Investigators Use for Reporting Accrual Data to NIH (New versus Old Table).**

NEW APPLICATIONS

New applicants are advised to complete all of the Sample Tables, with the exception of the progress reports (**Sample Tables 7A and 7B**) provided in the suggested format. Although the Sample Tables are not required, the reviewers may interpret their absence as a lack of data.

SPECIFIC INSTRUCTIONS

The following suggestions are provided to assist the applicant in addressing PHS 398 (Rev.09/2004 Interim Revision 04/2006) **Part I** (*Instructions*) **Preparing Your Application**, C. 6.RESOURCES (pages 33-34) and C.7.E. HUMAN SUBJECTS RESEARCH (pages 36-37). The suggestions are listed in the same sequence as the instructions in the PHS-398.

RESOURCES

Use the Resources Format Page (or create pages similar to the format page with the requisite information). See PHS-398 (Rev. 09/2004, Interim Revision 04/2006) **Part I** (*Instructions*), **Preparing Your Application**, C. 6.RESOURCES (pages 33-34) and integrate the following format suggestions to describe Resources.

Patient Catchment/Service Area

Describe the proposed patient catchment service area.

X Include a map of the patient catchment area, designating counties or zip codes from which approximately 80% of the cancer patients will be drawn.

X Describe the geographical area from which patients will be drawn. Include the demographics (age, race, sex, etc.) of the cancer patient population.

X Estimate the percent of oncologists in the service area who will be participating in the CCOP.

X Describe cancer care resources available in the service area that are not a part of the CCOP application (e.g., hospitals, clinics, physicians, cancer centers, medical schools, cooperative group affiliate program satellite hospital).

X Estimate the percent of the catchment/service area population that participates in HMOs or PPOs.

X Suggested page limit - 2 pages

Previous Relationships

X Is there a history of previous working relationships among some or all of the proposed participating physicians? If so, describe the following:

< previous patient practice relationships (e.g., referral, partnership, group practice, cross coverage);

< previous experience of some or all of the investigators in working together as a group in clinical trials (e.g., common Research Base, IRB, data management).

X Suggested page limit – 2 pages

Proposed Resources

To assist the applicant in providing material sufficient to permit adequate review of specific areas while maintaining clarity and brevity, we have included the following sample tables as suggested formats for providing specific information regarding proposed resources.

NOTE: With respect to the PHS 398 page limitation, each of the Tables 1 through 9B counts as **one page**, even though an applicant may include multiple pages for one or more of these Tables (e.g. 8 pages of Table 1 will count as 1 page against the page limitation referenced in the RFA-CA-07-025).

Sample Table 1	-	Components
Sample Table 2	-	Affiliates
Sample Table 3A	-	Participating Physicians
Sample Table 3B	-	Non-Physician Investigators (e.g.: PhD=s)
Sample Table 4	-	Personnel
Sample Table 5	-	Number of Newly Diagnosed Cancer Patients by Site
Sample Table 6A	-	Accrual to NCI Approved Cancer Treatment Clinical Trials
Sample Table 6B	-	Accrual to All Other Cancer Treatment Clinical Trials
Sample Table 6C	-	Accrual to NCI Approved Cancer Prevention/Control Clinical Trials
Sample Table 7A	-	Cancer Treatment Accrual (Progress Report)
Sample Table 7B	-	Cancer Prevention/Control Accrual (Progress Report)

Sample Table 8	-	Research Base Affiliation(s)
Sample Table 9A	-	Projected Accrual to NCI Approved Cancer Treatment Clinical Trials during the Next Year
Sample Table 9B	-	Projected Accrual to NCI Approved Cancer Prevention/Control Clinical Trials during the Next Year

NOTE: These tables should be included in the application in Resources, Progress Report and/or Human Subjects Research sections, as appropriate.

RESEARCH PLAN

There is no specific Form Page for the Research Plan. The research plan should include sufficient information needed for evaluation of the project. Follow the instructions provided in PHS-398 (Rev. 09/2004, Interim Revision 04/2006) **Part I** (*Instructions*) Research Plan (pages 34-36) and integrate the following format suggestions to describe the research plan.

Preliminary Studies/Progress Report

X **Past Experience**

< Describe your participation in treatment and cancer prevention/control clinical trials during the most recent funding period, or for new applicants, the last 3 years.

< Provide data on the number of patients the CCOP has in active follow-up on NCI-approved treatment clinical trials.

< Describe the outreach activities conducted by the CCOP to attract minority participants.

< Suggested page limit – 3 pages

X **Accrual to Cancer Treatment Clinical Trials**

< Enumerate the patient accrual for each physician, either a current CCOP member or a newly proposed member, to cancer treatment clinical trials. Narrative explanation may be attached, if needed, to fully document your experience. Indicate whether the clinical trial was funded or sponsored by the NCI, cooperative groups, cancer centers, public health departments, the American Cancer Society, or others. See Sample **Table 6A and 6B** which are intended to reflect the accrual activity by individuals of the CCOP.

< **Sample Table 7A** reflects the accrual to cancer treatment clinical trials for each year of the funding period for the CCOP.

X **Accrual to Cancer Prevention and Control Clinical Trials**

< Enumerate the accrual for each physician, either a current CCOP or a newly proposed member, to cancer prevention/control clinical trials. See **Sample Table 6C**. Describe your experience in cancer prevention/control research and related activities.

< **Sample Table 7B** reflects the accrual to NCI approved cancer prevention/control clinical trials for each year of the funding period for the CCOP.

< Suggested page limit – 3 pages

X **Evaluation of CCOP Performance by Affiliated Research Base(s)**

Include copies of reports from affiliated Research Base(s) describing CCOP performance over the previous funding period.

Research Design and Methods

Describe the proposed design of the CCOP (See PHS 398 (Rev. 09/2004, Interim Revision 04/2006) **Part I** (*Instructions*) Section I, **Preparing Your Application**, C.7.D. **Research Design and Methods,** page 36.

X **Operational Plan**

< If the CCOP has more than one component/affiliate (see sample Table 1 and Table 2 for definitions), provide a diagram of the CCOP components indicating distances between components/affiliates (including administrative office and shared resources) and location of proposed personnel.

< Describe the relationship of components/affiliates to each other and to the CCOP headquarters.

< Provide information on how the CCOP (physician and staff) will be organized and directed to facilitate participation in treatment and cancer prevention/control clinical trials. Include an organizational chart of how the group will function. Describe procedures for assuring implementation of the organizational plan.

< Describe plans for communication among physicians and components/affiliates and incentives for participation.

< Suggested page limit – 3 pages

X **Proposed Data Management**

< Describe the proposed data management plan, including:

- Who will have overall responsibility for data management;

- Source of records (e.g., hospital, office, clinic, registry);

- Who will be responsible for registering patients/subjects on study;

- How the information will flow (provide flow chart);

- Who will be responsible for information entry on primary patient record and on study forms (e.g., RN, MD, data manager, secretary);

- Who will be responsible for collecting and sending material (e.g., pathology slides, port

films, etc.) to the Research Base if required by a clinical trial; and

- What records (e.g., study flow sheets, forms, reminder slips) if any, will be placed on the patients charts.

< Describe the proposed quality assurance mechanism(s) for treatment and cancer prevention /control clinical trials. Who will have overall responsibility for quality control?

< Describe in detail the data management operations within and between component/ affiliates, investigators, and the central CCOP administrative office (if applicable).

< Will data be transmitted in batch form or as acquired to an intermediary institution/ central office of the Research Base(s)? Will this submission procedure be the same for each Research Base?

< Are computers to be used for data management (e.g., data file, reminder system, clinical trial data entry, transmittal to Research Base computers)? Are there provisions for electronic data transfer?

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< How will NCI/FDA requirements for control of investigational drugs be met?

< If applicable, describe the involvement of oncology nurses/data personnel in clinical trials not funded by the proposed CCOP award.

< Suggested page limit – 4 pages

X **Proposed Research Base Affiliation(s)**

< Describe previous working relationships with proposed Research Bases, if applicable. Include information on committee memberships and chairmanships as well as studies chaired. If one or more components participated as cooperative group affiliate program satellite hospital, specify the years.

< List the current Research Base affiliation(s) or, for new applicants, the proposed Research Base affiliation(s). A suggested format is shown in **Sample Table 8**.

< Suggested page limit – 2 pages

X **Cancer Treatment Clinical Trials Proposed for Use by the CCOP**

List the cancer treatment clinical trials to which the CCOP intends to recruit patients. See **Sample Table 9A** for suggested format.

X **Cancer Prevention and Control Clinical Trials Proposed for Use by the CCOP**

List the cancer prevention and control clinical trials to which the CCOP intends to recruit participants. See **Sample Table 9B** for suggested format.

X **Detailed Cancer Prevention and Control Description**

< Describe in detail two examples of NCI-approved cancer prevention and control clinical trials you intend to use from your affiliated Research Bases.

New applicants must provide implementation plans for at least two examples of NCI-approved cancer prevention/control clinical trials that utilize an intervention.

See **RFA-CA-07-025**, **Part II,** Section IV. Application and Submission Information, 2. Content and Form of Application Submission, Research Plan for all CCOP Group Applications, Section 3, Accrual Requirements, last paragraph.

< Describe the current and future outreach activities that the CCOP will conduct to attract minority participants.

Human Subjects Research

Create a section entitled "**Human Subjects Research**" immediately following the last entry in the Research Design and Methods section.

< Instructions for the Human Subjects Research section are in the PHS 398 (Rev. 09/2004, Interim Revision 04/2006), **Part II** (*Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan*).

As the first entry create a heading entitled "***Protection of Human Subjects***." See PHS 398 (Rev. 09/2004, Interim Revision 04/2006) **Part II**, (*Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan*) pages13-15 for the elements that should be addressed under this heading.

< Address the involvement of human subjects and protection from research risks relating to their participation in the proposed research plan, Applicants should refer to the PHS 398 (Rev. 09/2004, Interim Revision 04/2006) **Part I** (*Instructions*), **Decision Table** on page 38 to determine the relevant scenario that applies to their application. The majority, if not all, CCOP applicants will need to address the topics outlined under Scenario F.

Create a heading entitled "***Data and Safety Monitoring Plan***."

< A CCOP applicant is not directly responsible for the formulation of data safety and monitoring plans and/or boards. However, the CCOP applicant must discuss its requirement to follow the data safety and monitoring plan(s) for each of the Research Bases with which it is affiliated. The application should describe how the CCOP implements the Research Base(s) data safety and monitoring plan(s).

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See PHS 398 (Rev. 09/2004, Interim Revision 04/2006) **Part II** (*Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan*) pages 14-15 for more information on the elements of data safety and monitoring that should be addressed in the application.

Inclusion of Women and Minorities

Create a section heading entitled "***Inclusion of Women and Minorities***," and place it immediately following the "Protection of Human Subjects" section. See PHS 398 (Rev. 09/2004, Interim Revision 04/2006), **Part II** (*Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan*) pages 16-20.

NOTE: Additional information is required from applicants (i.e., Research Bases) that include NIH-defined phase III clinical trials in their proposed research. See **Part II** (*Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan*) page 17.

NOTE: CCOP applicants should include a comment in this section that while they participate in

NIH-defined phase III, accessed through their Research Bases, the CCOP is not involved in the design and/or analysis of these trials, nor does it have a complete data set on any clinical trial in which it participates. Therefore, this additional requirement is not relevant or applicable to the CCOP application.

Inclusion of Children

Create a section entitled "***Inclusion of Children***." This section should immediately follow the last entry in Inclusion of Women and Minorities section.

< For applicants that include a pediatric component, the plan for including children should be described. See **Part II** (*Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan*) pages 21-22 for additional guidance on information to include in your description.

< If children will be excluded from the research, the applicant must present an acceptable justification for the exclusion. For the applicants that do not include a pediatric component see **Part II** (*Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan*) Justifications for Exclusion of Children on pages 21-22 (see 4.b.).

Resource Sharing

(1) Data Sharing Plan

All applicants must address their data-sharing plan in their application. Data sharing pertains to both published and unpublished but **complete data sets**. Investigators should refer to http://grants.nih.gov/grants/policy/data_sharing/) for guidance on addressing this application requirement. See PHS 398 (Rev. 09/2004, Interim Revision 04/2006)) **Part I** (*Instructions*), Resource Sharing, page 41.

NOTE: While a CCOP application collects data on individual patients/participants entered onto clinical trials, the Research Base(s) is the entity that receives the complete data set for each clinical trial for which it is the lead group. The Research Base(s) will ultimately share these data through publications, presentations and other mechanisms deemed to be appropriate.

Describe the CCOP's plan to share data. Include a brief paragraph describing how the CCOP shares its data with its affiliated Research Bases and/or through other mechanisms, if applicable. Describe the process the CCOP follows to protect the rights and confidentiality of patients/participants.